



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Next-Generation Sequencing Technology, Data Formats Standardization and Promotion of Interoperability Protocols; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), is announcing a public workshop entitled "Next-Generation Sequencing (NGS) Technology, Data Format Standardization and Promotion of Interoperability Protocols." The goal of this public workshop is to facilitate establishing protocols for ensuring the safety and quality of next-generation sequencing (NGS)-related information without sacrificing scientific merit or interfering with innovative processes. The purpose of the workshop is to engage NGS stakeholders in a forum to discuss the current use of the technology and the development of data standards of NGS-related information.

Date and Time: The public workshop will be held on September 24 and 25, 2014, from 8:30 a.m. to 4:30 p.m.

Location: The public workshop will be held at the National Institute of Health Campus, 9000 Rockville Pike, Bldg. 35, rm. 610, Bethesda, MD 20892. Pre-registered participants will receive additional information on parking and public transportation with their email registration confirmation.

Contact Person: Khaled Bouri, Office of Regulatory Science and Innovation, Food and Drug Administration, 10903 New Hampshire Ave., rm. 4164, Silver Spring, MD 20903, 301-796-8476, email: Khaled.Bouri@fda.hhs.gov.

Registration: Please go to <http://ngs-data-standardization.eventbrite.com> to register. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration will be confirmed by email. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m. This workshop will also be accessible via Webcast by following this link:
<https://collaboration.fda.gov/NGSStandards/>.

If you need special accommodations due to a disability, please contact Khaled Bouri (see Contact Person) at least 7 days in advance.

Transcripts and Additional Information About the Workshop: The workshop agenda and additional background materials will be accessible at:
<http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm227840.htm>. Please be advised that as soon as possible after the public workshop a transcript will be available at the same Web site. Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Building, Rockville, MD 20857.

Dated: April 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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